

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 524**

**Ophthalmic and Topical Dosage Form New Animal Drugs; Selamectin**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

DMB

Display Date	7-20-00
Publication Date	7-21-00
Certifier	SNR/ase

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for topical veterinary prescription use of selamectin solution for the additional indication for control of intestinal hookworm and roundworm infections in cats.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540.

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed supplemental NADA 141-152 that provides for topical veterinary prescription use of Revolution™ (selamectin) in dogs and cats for the additional indication for control of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. The supplemental NADA is approved as of June 13, 2000, and the regulations are amended in 21 CFR 524.2098 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food

and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning June 13, 2000, because the application contains substantial evidence of effectiveness of the drug involved or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

#### **List of Subjects in 21 CFR Part 524**

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

#### **PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 524 continues to read as follows:

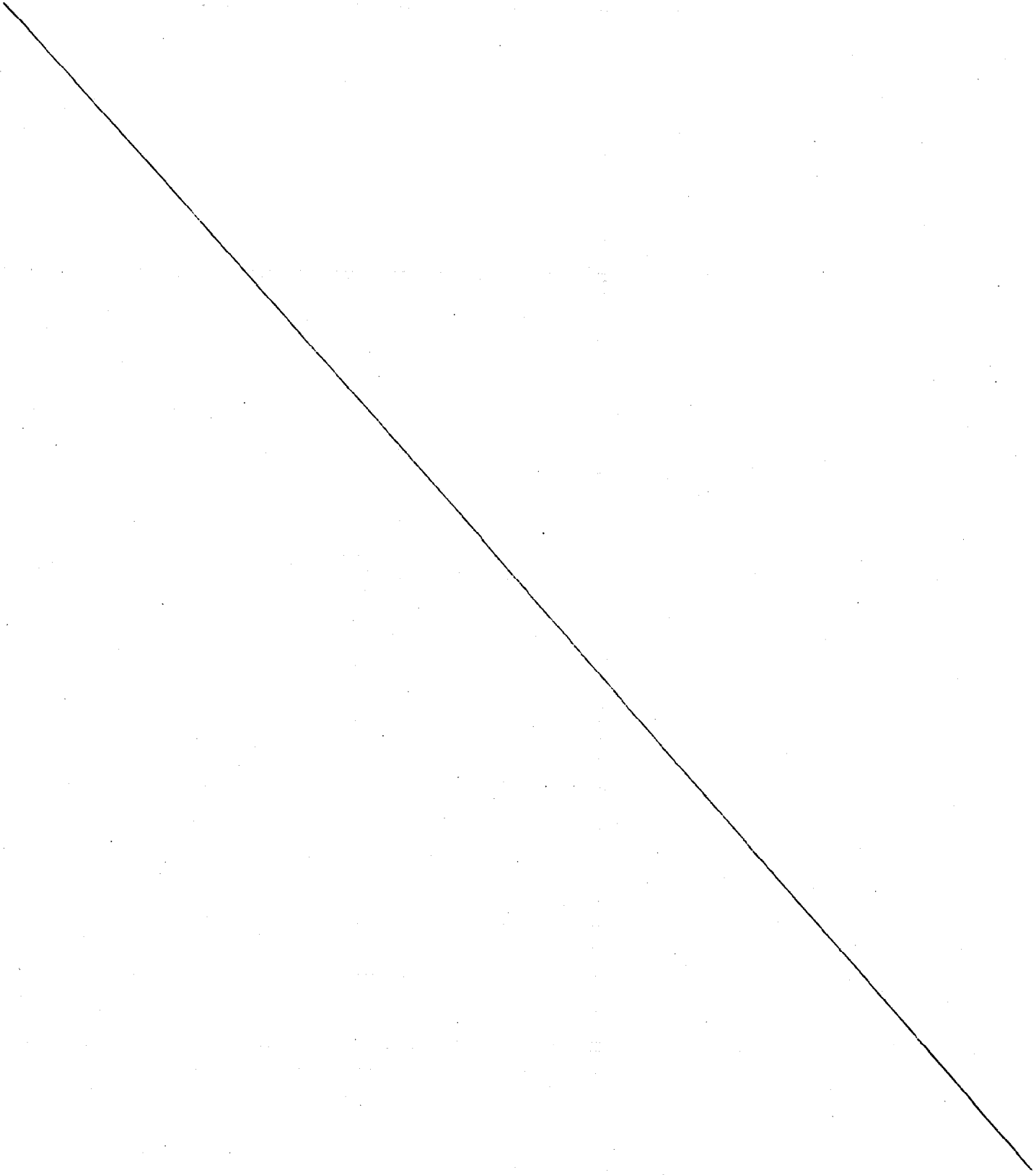
**Authority:** 21 U.S.C. 360b.

2. Section 524.2098 is amended by revising the third sentence in paragraph (d)(2) to read as follows:

§ 524.2098 Selamectin.

\* \* \* \*

(d) \* \* \*



(2) \* \* \* Treatment and control of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. \* \* \*

\* \* \* \* \*

Dated: 7/3/00

July 3, 2000



David R. Newkirk,  
Acting Director, Office of New Animal Drug Evaluation,  
Center for Veterinary Medicine.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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